AI and Healthcare in India: Looking Forward

Roundtable Report

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This Report provides an overview of the proceedings of the Roundtable on Artificial Intelligence (AI) and healthcare in India: Looking Forward (hereinafter referred to as 'the Roundtable'), conducted at The Energy Resource Institute (TERI), in Bangalore on November 30, 2017. The Roundtable consisted of participants from different sides of the AI and healthcare spectrum, from medical practitioners, medical startups to think tanks. The Roundtable discussed various questions regarding AI and healthcare with a special focus on India.

The Roundtable discussion began with the results of the primary research conducted by CIS on AI and healthcare. CIS, in its research, identified three main uses of AI in healthcare - supporting diagnosis, early identification and imaging diagnosis. The benefits of AI were - faster diagnosis, personalised treatment and the bridging of manpower gap. Questions regarding medical ethics, privacy, regulatory certainty, social acceptance and trust were identified as the issues or barriers to the use of AI in healthcare. The cases chosen for study were IBM Watson (used by Manipal Hospitals in India), Deep Blue (used by the NHS UK), Google Brain (used in the Aravind Healthcare in India) and Sig-Tuple (an AI based pathologist assistant). CIS wished to explore the ethical side of this topic,the question of public interest and the need to protect the patient from harm. The session was then opened for discussion on the following issues.

Issue 1. Present and future uses of AI and healthcare and the significant challenges in developing, adopting and implementing AI

This part of the session involved a discussion on how the participants were presently using AI in their field and how they planned to in the future. One of the ways in which AI was being used was through chatbots that provided mental health support. Through this system any person could chat with an AI enabled system anonymously and the bot would provide empathetic support and even suggest practitioners to consult. However, these chatbots were not designed to provide diagnosis and issues of more serious nature were transferred to the doctors. The Woebot a talk therapy chatbot created by the psychologists and AI experts at Stanford was the example of such a system. People were more open to sharing their problems with chatbots as these systems were found to be more empathetic towards their concerns. The main reason for trust was the feature of anonymity and privacy. Their names or any other personal information was not collected nor was there was a sign up feature, which made people more open to sharing their sensitive personal information.

Secondly, AI was used to monitor the patients in the ICU which then notified the doctor of any anomaly in the patient's vitals. AI was also used therapeutically as in the case of Implantable Cardiovascular Defibrillator (ICD) that monitored the heart rate and automatically administered shocks in case an abnormality was detected.

The third use was in cognitive computing such as IBM's Watson in Oncology. The AI in this case analysed the data and the research evidence, and thereby improved the quality of the report, which increased the trust and confidence of the patients.The patients were fully aware of the process and their express consent was taken. Due care was also taken to maintain the anonymity of the patient data.

Hence after the discussion by the participants using AI, the present uses of AI were stated to be predictive, monitoring, therapeutic and assistive. The participants agreed that the system was doing a better job of disease identification and reduced drudgery and manual intervention with the use of predictive as was well as co-relative data. One of the participants also enumerated with an example, of how chatbots could provide empathy to people having mental health problems, to the extent that it prevented a person from causing self harm. The anonymity and privacy also played a role in increasing the trust of the people and it was free from the bias that might arise in the case of human intervention.

The participants at the Roundtable agreed that the system was not foolproof and that there were many concerns that needed to be addressed. The first was the issue of having a standard design guideline. The second was the information asymmetry between the doctors who use the system and the coders who build the system. Third issue was the question of liability, ethical risks and moral hazards arising out of any decision made by the patient in view of the report or findings of the AI system. The final issue was of Data Residency and security that was raised by the startups. The legal barriers formulated by the countries with respect to the flow of data, prevented people from accessing it outside the country. Since most of the data was on cloud, it did not have any territorial boundary but the data protection laws prevented interoperability. It also made the startups wary of the cost and consequences of dealing with medical data.

Conclusion: This session concluded with the consensus of all the panelists that the use of the AI in healthcare should be restricted to prediction and assistance and should in no way to provide diagnosis or replace a doctor. The need was for augmentation and not replacement. The need to keep privacy and anonymity at the forefront was also re-emphasised. The need to address the problems of moral hazard and accountability, the need for a standard design guideline for the systems in the future, along with proper training and sensitisation of the doctors using AI in their practice were also agreed upon.

Issue 2. Optimising Ethics, Innovation,Principles and Regulation

The next part of the Roundtable dealt with the pertinent question of drawing a fine line between innovation and ethics. It was stated that it was difficult for law to keep up with technology and preempt its misuse. However, this did not mean that there was an absence of any legal framework. The existing legal frameworks include the Regulations of the Data Protection Rules, Section 43A of Information Technology Act, and the privacy judgement (Justice K. S. Puttaswamy (Retd.) and Anr. vs Union Of India And Ors) which states about bodily autonomy, these could be used in the context of AI and health. As of now, AI in healthcare is being used in a controlled atmosphere. Concerns were raised on possible monumental changes in AI and healthcare in when it would be used amass. A similarity was drawn to the problem with the Aadhaar card where after repeated rounds of testing the UIDAI's system was found to be not as efficient as it seemed when tested with a small population.The problems in the system emerged only when the system was used with the entire Indian population. The panelists felt that there needed to be some amount of skepticism with regard to the use of technology. The questions regarding the potential harm that could be caused by the data related to health that is fed into the AI system were raised in light of economic, reputational and even physical harm. Although the AI system was unbiased, but there was a possibility of biases with respect to case data collection and entry. As the primary data was entered by humans the bias at the data entry level would cause the AI to work accordingly. There is also the issue of people overlooking the concerns and trusting the AI reports blindly like how the judges, for example, trusted the DNA results or brain mapping results, even though it is believed that theses results are not conclusive.

It was agreed that there was a need for higher standards and stricter principles with respect to data on sensitive personal information. An example of a body that was working towards this end was the Institute of Electrical and Electronic Engineers (IEEE) with its ethically aligned design initiative for autonomous and intelligent systems. It attempts to define and lay down the bare minimum principles that developers and designers should bear in mind while making autonomous systems.

Another pertinent question raised by the startups was the difficulty in conducting clinical trials and the lack of a clear regulation to adhere to. In the case of liability the question pertained to the person who would be liable - whether it would be the caregiver/doctor or the developer. It was stated that software and code not being technology agnostic having no one size fits all system, the creator of the software should be an agent that could be regulated. Currently, however the doctor is the only stakeholder who is held liable.

The need for an ethical angle was drawn as the safety of the lives of the patients were at stake. The discussion then proceeded to the topic of how the State governed the medical profession. The question of accountability of the doctor was another concern that was raised. Especially in the cases where due to a glitch in the AI system or due to a data entry mistake the doctor was not able to give the correct treatment. In these cases although the fault was not of the doctors he would be held liable. With respect to this it was pointed out that the European Union was defining boundaries where AI would not be allowed to take over and healthcare was identified as one such area where the boundary was required.

With respect to the problem of security as a challenge, the question of Data Residency re-emerged. The data laws of the EU, for example, had strict compliance parameters which at times deterred innovation. Another issue on the compliance and innovation debate was that of clinical trials. While it is an understandable concern with respect to drugs, when used in the field of technology, it could result in obsolescence by the time the technology was approved. Startups were of the opinion that the medical practitioners were less trusting towards the startups which did not have an approval from a national or international authority. With respect to medical devices on 15 devices were regulated by the Drug Controller under Schedule F of the Drugs and Cosmetic Rule 1945 whereas the rest were left to be used without regulatory approval. A possible solution was floated in which the doctors could partener with the startups and help them conduct the trials. Internal discussions within CIS after the roundtable have also also informed the author that the Indian Medical Device Rules, 2017 will most likely come into force in January 2018 and will apply to almost all medical devices sold in the nation.

A regulatory sandbox similar to the one for startups was suggested as a solution to the problem of regulation. A regulatory sandbox is a kind of a testing box where there are relaxed regulations to allow the product to be launched. Through this the government could incentivise people working in the field of AI and health to provide safe spaces as well as certification (hence providing the needed approval to use the services in the market). This system has already been adopted in Japan where there are AI specific regulatory sandboxes for autonomous driving and health. The World Bank's Development Marketplace is another example of a effective system to foster innovation.

The next question was regarding the identity of the regulating authority. The possible options were the Medical Council of India, of the Drug Controller or an entirely new entity established for this specific purpose. The discussion also went into the two types of regulatory entities in India - one that concerned itself with all aspects of a specific subject, such as the Competition Commission of India, and the other that was dedicated to only one subject such as the Telecom Regulatory Authority of India (TRAI) which dealt with all issues relating to telecommunication. Considering the fact that AI was not limited to any one subject or aspect, there is a need for self regulation. A possible solution suggested to this problem was the use of different regulators for different aspects, such as for the medical aspect Medical Council of India (MCI) and and for the data aspect a new regulator under the Data Protection Bill.

It was stated that there were some discussions and dialogues happening in India, where especially with regard to the department of biotech, in, the Department of Science and Technology was offering research grants in the field of technology and healthcare.

There was a consensus on the high level of care needed in handling personal and sensitive data of the patients and stricter principles for governing their collection same. As a result of the discussion a few guiding principles were highlighted:

1. Do no harm - ensuring that the collection of data does not cause any harm
2. Choice of sharing/ Consent - need for a much better structure regarding it
3. Burden of compliance on data collecting authority - the person collecting the data has more power than the one providing the data, as the authority has greater power to manipulate the data

4. Trust the doctor - the doctor should be the final decision maker
5. A modification of 'do not harm principle' in the form of certain parameters that the system should not cross (such as not giving diagnosis and the not substituting the doctor)
6. Abstinence from the use of information that can identify a person
7. Promotion of human to human interaction - there should be human involved in the final decision making

Conclusion: The Roundtable agreed on the need for a framework in place to curb the regulatory oversight. The insistence on clinical trials and the lack of understanding on part of the Indian Government and insufficient funding from them were some of the other problems that needed attention.

Issue 3. Practical Considerations - Electronic Medical Records (EMR)

The session later shifted to a discussion on the issue of practical consideration of use and storage of data. The example of curated digital intervention in healthcare by the World Bank was discussed where the data was curated from the Indian hospitals. The rules were determined by the World Bank and the data was provided by the hospitals. With respect to the availability of the data, Singapore and Israel were stated to have an open network, in these countries the data of each patient was released without disclosing the identity or any personal information of the patient. This highlighted the the lack of open medical data in India and how this was creating a barrier for AI related startups to cater to the Indian demographic. Although there were scattered examples such as the state of Tamil Nadu and the National Cancer Registry (which had a commendable amount of data on Indian Cancer patients), etc they were not sufficient. The need to make better use of granular data was also annotated, similar to the way data was maintained by the Department of Labour in the United States where the the nature of the future workforce was predicted by using the number of college enrollments.

It was concluded that there was a dearth of guidelines regarding data collection in India, especially in healthcare in addition to errors of data entry and tabulation.

Conclusion: The Roundtable agreed on the need for a proper guidelines for data collection in India as well as the availability of patient data without compromising on the privacy and security of the patient.

Conclusion

The Roundtable was an insight into the issue and concerns of the use of AI in healthcare and the resulting discussion shed light on the present use of AI in the Indian healthcare system as well as the future concerns. It discussed some pertinent questions with respect to the use of AI in healthcare, be it in the form of cognitive assistance, chat bots or assistants. The use of AI raises a lot of ethical questions that need to be addressed. One of the solutions that came out of the discussions was the establishment of a strong framework of guidelines and data regulations. It was agreed that the main use of AI was to assist the doctors and not to provide diagnosis or replace them.